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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,211	10/30/2006	Bakulesh Mafatlal Khamar	574152000400	9175
25227 7590 10/28/2008 MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD			EXAMINER	
			SWARTZ, RODNEY P	
SUITE 400 MCLEAN, VA	22102		ART UNIT	PAPER NUMBER
			1645	
			MAIL DATE	DELIVERY MODE
			10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/565,211 KHAMAR, BAKULESH MAFATLAL Office Action Summary Examiner Art Unit Rodney P. Swartz, Ph.D. 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 9July2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 22-48 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 22-48 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/S5/05)
 Paper No(s)/Mail Date \_\_\_\_\_\_\_.

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

 Applicant's Response to Office Action, received 9 July 2008, is acknowledged. Claims 23 and 48 have been amended.

2. Claims 22-48 are pending and under consideration.

#### Rejections Maintained

The rejection of claims 22-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained.

Applicant argues that the specification is sufficient support for the claimed inventions and that the EPO granting of counterpart claims also indicates sufficient support.

The examiner has considered applicant's argument, but does not find it persuasive. The instant claims are drawn to methods of treatment, management or prevention of lung disease by administration of "Mycobacterium w or a constitutent of Mycobacterium w". However, as put forth in the previous office action, while the specification does recite 8 different preparations, the specification does not indicate which preparation was actually utilized. Therefore, there remains insufficient support for the claimed inventions because it is unclear which, if any, of the recited preparations was actually utilized and produced the claimed results.

### Conclusion

- Claims 22-48 are finally rejected.
- Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00
  AM to 7:30 PM EST. Thursday is the examiner's work at home day.

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If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./ Primary Examiner, Art Unit 1645

October 28, 2008